§ 173.196 Infectious substances (etiologic agents).

(a) Authorized packagings and components are as follows:

(1) Inner packagings comprising:

(i) A watertight primary receptacle;

(ii) A watertight secondary packaging; and

(iii) An absorbent material must be placed between the primary receptacle and the secondary packaging. If multiple-primary receptacles are placed in a single secondary packaging they must be wrapped individually to ensure that contact between them is prevented. The absorbent material, such as cotton wool, must be sufficient to absorb the entire contents of all primary receptacles.

(2) An outer packaging must be of adequate strength for its capacity, mass and intended use.

(b) Each package for infectious substances must be capable of passing the tests specified in §178.609 of this subchapter.

(c) Packages consigned as freight must be at least 100 mm (3.9 inches) in the smallest overall external dimensions.

(d) For all packages containing infectious substances, an itemized list of contents must be enclosed between the secondary packaging and the outer packaging.

(e) Although exceptional cases, such as whole organs, may require special packaging, the great majority of infectious substances can and must be packaged according to the following guidelines.

(1) *Lypholized substances.* Primary receptacles include flame-sealed glass ampoules or rubber-stopped glass vials fitted with metal seals.

(2) *Liquid or solid substances*—(i) *Substances shipped at ambient temperatures or higher.* Primary receptacles include those of glass, metal or plastic. Positive means of ensuring a leakproof seal, such as heat seal, skirted stopper or metal crimp seal must be provided. If screw caps are used, they must be reinforced with adhesive tape.

(ii) *Substances shipped refrigerated or frozen (ice, pre-frozen packs, dry ice).* Ice or dry ice must be placed outside the secondary packagings. Interior supports must be provided to secure the secondary packagings in the original position after the ice or dry ice has dissipated. If ice is used, the packaging must be leakproof. If dry ice is used, the outer packaging must permit the release of carbon dioxide gas.

(iii) *Substances shipped in liquid nitrogen.* Plastic primary receptacles capable of withstanding very low temperatures must be used. Secondary packaging must also withstand very low temperatures and in most cases will need to be fitted over individual primary receptacles. Requirements for shipment of liquid nitrogen must also be observed.

(f) Whatever the intended temperature of shipment, the primary receptacle or secondary packaging used for infectious substances must be capable of withstanding, without leakage, an internal pressure which produces a pressure differential of not less than 95 kPa (14 psi) and temperatures in the range of −40 °C to +55 °C (−40 °F to +131 °F).

(g) The requirements of this section supplement the requirements of the Department of Health and Human Services contained in 42 CFR part 72.

(h) *Exceptions.* The following substances are not subject to any requirements of this subchapter if the items as packaged do not contain any material otherwise subject to the requirements of this subchapter.

(1) Diagnostic specimens.

(2) Biological products.

[Amdt. 173–224, 55 FR 52634, Dec. 21, 1990, as amended by Amdt. 173–241, 59 FR 67511, Dec. 29, 1994]

§ 173.197 Regulated medical waste.

(a) Regulated medical waste must be packaged in packagings conforming to the requirements of part 178 of this subchapter at the Packing Group II performance level. The packagings must be:

(1) Rigid;

(2) Leak resistant;

(3) Impervious to moisture;

(4) Of sufficient strength to prevent tearing or bursting under normal conditions of use and handling;

(5) Sealed to prevent leakage during transport;

(6) Puncture resistant for sharps and sharps with residual fluids; and